

Rejection Under 35 U.S.C. § 103

Claims 1-22 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Touitou (U.S. Patent No. 5,716,638) in view of Peart *et al.* (WO 00/24362) and Vachon (XP-000965573) in further view of Allison's Apothecary.

The Applicant respectfully disagrees and traverses this rejection. Touitou in view of Peart *et al.* and Vachon in further view of Allison's Apothecary do not teach or suggest the claimed invention, nor is there any suggestion to one of ordinary skill in the art that there is a reasonable likelihood of success of the present claimed invention. Additionally, unexpected results and long-felt need are indicia of nonobviousness.

The burden of establishing a *prima facie* case of obviousness lies with the Examiner. In determining obviousness, one must focus on the invention as a whole. *Symbol Technologies Inc. v. Opticon Inc.*, 19 U.S.P.Q. 2d 1241, 1246 (Fed. Cir. 1991). The primary inquiry is: "Whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have had a reasonable likelihood of success Both the suggestion and the expectation of success must be found in the prior art, not the applicant's disclosure." *In re Dow Chemical*, 5 U.S.P.Q. 2d 1531 (Fed. Cir. 1988). When all the prior art is considered together, a person having ordinary skill in the art must have a sufficient basis for the necessary predictability of success to sustain a rejection under 35 U.S.C. § 103. See *Ex parte Novitski* 26 U.S.P.Q. 2d 1389 (Bd. Pat. App. & Int. 1993) citing *In re Clinton*, 188 U.S.P.Q. 365 (CCPA 1976).

The Examiner states that Touitou teaches a pharmaceutical composition for delivery to tissues. However, only topical dosage forms are disclosed. It does not teach a

pharmaceutical composition **suitable for rapid delivery to a lung of a subject** and subsequently to the bloodstream; nor does it teach a stable clear solution near the solubility point of delta-9-tetrahydrocannabinol such that the partitioning is enhanced. Touitou further discloses a composition with phospholipids, which again is not a solution meeting the limitations of Applicant's claims. Touitou does not suggest or disclose any motivation to produce its composition in an aerosolized form suitable for inhalation to the lungs.

Here, Applicant uses functional language to limit its composition to one suitable for delivery to the lungs so as to allow transfer of the delta-9-tetrahydrocannabinol into the bloodstream. Such a composition is distinct from the topical forms taught by Touitou. Functional language in a claim for a composition is a proper limitation. Moreover, MPEP § 2173.05(g) states “[a] functional limitation is often used in association with an element, ingredient or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step.” Claim 1, as amended, is not taught or suggested by the cited references.

The Examiner states that the composition would be obvious because Touitou discloses a composition with tetrahydrocannabinol, water, propylene glycol, and ethanol (among other things), Peart *et al.* discloses tetrahydrocannabinol with ethanol and glycol and Vachon discloses tetrahydrocannabinol with water and glycol. The Examiner further noted that “it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose.” The facts in the present invention are distinguishable from the facts of *In re Kerkhoven*; in that case, the court went on to add that the idea of combining the ingredients flowed logically from the prior

art because *it required no more than the mixing together of two conventional spray-dried detergents*. See *Ex parte Bokisa*, 1997 WL 1897871 at *3 (Bd. Pat. App. & Inter. 1997) (holding *In re Kerkhoven* is inapplicable to a factual situation in which a suggestion in the prior art that one of the two combined compositions produces undesirable side-effects). The addition of water to the disclosure in Peart *et al.*, making Touitou suitable for aerosolization or making Vachon shelf stable is far more than mixing together two ingredients.

Indeed, Peart *et al.*, teaches away from adding water to the composition disclosed. Peart *et al.*, in the specification stated the “*non-aqueous* formulation of the present invention is excellent with respect to chemical degradation.” Further, Peart *et al.* stated that the stability is due to the *specific formula disclosed* (non-aqueous). It is well known in the art that the addition of water to a hydrophobic molecule like delta-9-tetrahydrocannabinol will increase instability.

There is no suggestion in the disclosures of any of the references that would suggest that stability of the THC composition suitable for aerosolization would be accomplished by the addition of water. Moreover, Vachon, which was published more than 25 years ago, specifically asks the question of how aerosolized THC with water can be stabilized without refrigeration. There has been no answer to this question until the present invention. The long-felt need of the present invention rebuts obviousness. The data at pages 5-6 and 10 of the present application support the unexpected results of the claimed invention.

Although Peart *et al.* and Vachon, taken together, teach delta-9-tetrahydrocannabinol, water, ethanol and glycol, they do not suggest the claimed

composition. The Peart *et al.* composition, without water, does not have the increased partitioning, which gives the claimed composition an important advantage. Likewise, the composition disclosed in Vachon is not stable at room temperature. It is recognized that in the chemical arts, "a compound need not excel over prior art compounds in all common properties Evidence that a compound is unexpectedly superior in one of a spectrum of common properties. . . can be enough to rebut a prima facie case of obviousness." *In re Chupp*, 2 U.S.P.Q. 2d 1437, 1439 (Fed Cir. 1987). The increased partitioning is an unexpected result over the cited references.

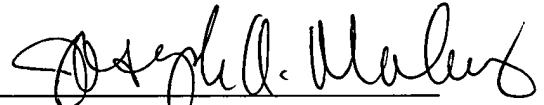
Therefore, the cited references do not teach or suggest the claimed invention, nor do they suggest to one of ordinary skill in the art that there is a reasonable likelihood of success. Also, the Office Action has cited no pertinent reference suggesting to one of ordinary skill in the art the interchangeability of elements of the present claims. And furthermore, unexpected results and long-felt need are indicia of nonobviousness. The 35 U.S.C. § 103(a) rejection is therefore improper. Reconsideration and withdrawal of this 35 U.S.C. §103(a) rejection is requested.

With entry of the above Amendment and in view of the foregoing remarks, it is respectfully submitted that claims 1-22 are in condition for allowance. It is respectfully submitted in view of the foregoing Remarks that all of the objections and rejections in the Office Action dated November 19, 2001 have been overcome and should be withdrawn. Accordingly, reconsideration and withdrawal of the outstanding rejections and allowance of claims 1-22 is respectfully solicited. Applicant respectfully requests early and favorable notification to that effect.

Respectfully submitted,

Dated: February 19, 2002

By:

A handwritten signature in cursive script, appearing to read "Joseph A. Mahoney", written over a horizontal line.

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Version with Markings to Show Changes Made to the Claims

1. (Twice Amended) A stable, aerosolizable composition that is pharmaceutically suitable for rapid bronchial delivery [by inhalation by a subject] to [the] a lung[s] of a subject, [and subsequently to the bloodstream,] the composition comprising a therapeutically effective amount of delta-9-tetrahydrocannabinol in a pharmaceutically-acceptable semiaqueous solvent comprising an alcohol, water and a glycol, [in] provided that: [the amounts thereof are sufficient.]
 - (i) upon aerosolation [to aerosolize] the composition to a mean mass median aerodynamic diameter in the range from about 1 up to about 10 μ M; and
 - (ii) the ratio of the alcohol, water and glycol produces [to enhance partitioning by producing] a stable clear solution near the solubility point of the delta-9-tetrahydrocannabinol such that upon administration to the lung, the partitioning of the delta-9-tetrahydrocannabinol from the solvent is enhanced so as to reach the bloodstream.